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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Fisher *et al.*
Serial No. : 10/055,475 Examiner : Dunston, Jennifer Ann
Filed : January 22, 2002 Group Art Unit: 1636
For : USE OF MDA-5 AS AN ANTIVIRAL AND
ANTIPROLIFERATIVE AGENT

RESPONSE

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July 13, 2004

Date of Deposit

Lisa B. Kole

Attorney Name

Signature

35,225

PTO Registration No.

July 12, 2004

Date of Signature

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In response to the Restriction Requirement dated June 16, 2004, please
consider the following remarks. As this response is filed within one month of the mailing
date of the Restriction Requirement, it is timely filed. However, should any extension of
time be required, this paper should be regarded as a petition for the period of extension
necessary, and any fee required may be charged to Deposit Account No. 02-4377.

The Examiner has required that Applicants elect one of the following groups of claims, which are contended to represent separate inventions:

Group I. Claims 1-9, 30-34 and 35-40, drawn to methods of protecting a subject against contracting a viral infection and methods of limiting a viral infection in a subject by administration of MDA-5 protein;

Group II. Claims 1-3, 10-18, 30-34 and 41-49, drawn to methods of protecting a subject against contracting a viral infection and methods of limiting a viral infection in a subject by administration of mda-5 nucleic acid;

Group III. Claims 1-3, 19-27, 30-34 and 50-58, drawn to methods of protecting a subject against contracting a viral infection and methods of limiting a viral infection in a subject by administration of an agent that increases the activity of an mda-5 promoter;

Group IV. Claims 1-3, 28-34 and 60, drawn to methods of protecting a subject against contracting a viral infection and methods of limiting a viral infection in a subject by administration of an agent that acts on MDA-5 protein to increase the functional activity of the protein;

Group V. Claims 61-66, drawn to methods of inhibiting cell proliferation in a cell population *in vitro* by administration of MDA-5 protein;

Group VI. Claims 61-66 and 77-82, drawn to methods of inhibiting cell proliferation in a cell population *in vivo* by administration of MDA-5 protein;

Group VII. Claims 67-76, drawn to methods of inhibiting cell proliferation in a cell population *in vitro* by administration of mda-5 nucleic acid in an expressible form;

Group VIII. Claims 67-76 and 83-92, drawn to methods of inhibiting cell proliferation in a cell population *in vivo* by administration of mda-5 nucleic acid in an expressible form;

Group IX. Claim 93, drawn to an isolated mda-5 nucleic acid;

Group X. Claim 94, drawn to a method of sensitizing a cell to a growth-inhibitory effect of a protein kinase C inhibitor;

Group XI. Claim 95, drawn to a viral vector comprising two cancer-inhibitory genes, one of which is operably linked to a mda-5 promoter;

Group XII. Claim 96, drawn to an isolated protein (SEQ ID NO:7);

Group XIII. Claim 97, drawn to an isolated nucleic acid (SEQ ID NO:8); and

Group XIV. Claim 98, drawn to an isolated protein (SEQ ID NO:9).

With regard to Groups I-IV, the Examiner states:

Inventions of Groups I-IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different mechanisms of protecting a subject against a viral infection: by administration of MDA-5 protein directly (Group I), a nucleic acid capable of expressing MDA-5 protein (Group II), an agent that increases the activity of an mda-5 promoter (Group III), and an agent that acts on MDA-5 protein to increase the functional activity of the protein (Group IV). Claim 1 link(s) inventions of Groups I-IV. The restriction requirement between the linked inventions is subject to the non-allowance of the linking claim(s), claim 1. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application.

Applicants respectfully disagree with the position that the inventions of Groups I-IV are unrelated. Claim 1 reads as follows:

1. A method of protecting a subject against contracting a viral infection comprising administering, to the subject, an effective amount of an agent which increases the level of MDA-5 protein activity in the subject.

The restriction requirement treats, as unrelated inventions, four *causally linked* ways of increasing MDA-5 protein activity. Group III relates to increasing *mda-5* promoter activity, which would result in an increase of *mda-5* mRNA and MDA-5 protein. Group II relates to administering *mda-5* nucleic acid which (in expressible form, see Claim 10) also increases *mda-5* mRNA and, consequently, MDA-5 protein. Group I provides for administering MDA-5 protein itself. Group IV relates to increasing the activity of MDA-5 protein. These groups can hardly be regarded as being unrelated.

Applicants invite the Examiner's attention to paragraph 51 of the instant specification, which clearly articulates the relatedness of Groups I-IV:

Examples of agents which may be used to increase the level of MDA-5 protein, or MDA-5 protein-mediated RNA degradation, or ATPase activity in a subject include, but are not limited to, (i) MDA-5 proteins; (ii) *mda-5* nucleic acids, in expressible form, which encode MDA-5 proteins; (iii) agents which increase the activity of an *mda-5* promoter or that stabilize MDA-5 encoding mRNA; (iv) agents which increase the RNA degradation activity of MDA-5 protein; and (v) agents which increase ATPase activity of the MDA-5 protein.

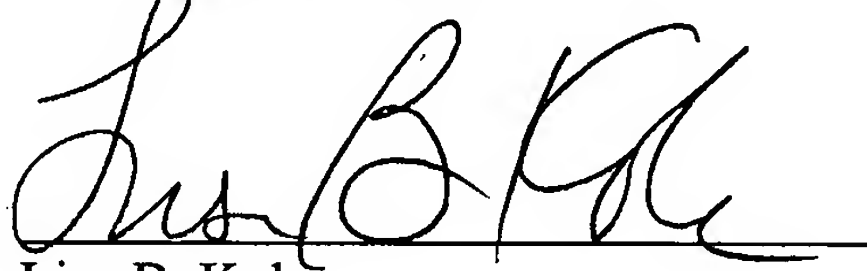
If "inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects," then clearly Groups I-IV *are* related because they all have the same effect – they increase MDA-5 protein activity.

Therefore, Applicants should be allowed to prosecute the claims of Groups I-IV together; this would be the preferred election. It is earnestly requested, in view of the foregoing reasons, that the Examiner reconsider the restriction requirement and modify the requirement as suggested by Applicants to combine Groups I-IV, which would create a new group containing claims 1-60.

Because Applicants are required to elect one Group of claims in order to be responsive to the Official Action. Applicants elect Group III, with traverse as set forth above.

Respectfully submitted,

BAKER BOTTS L.L.P.

A handwritten signature in black ink, appearing to read 'Lisa B. Kole', written over a horizontal line.

Lisa B. Kole

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Enclosures